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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,374	08/25/2006	Tomoyuki Nemoto	20692/0205266-US0	3271

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EXAMINER

LISTVOYB, GREGORY

ART UNIT	PAPER NUMBER
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1796

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,374	Applicant(s) NEMOTO ET AL.	
	Examiner GREGORY LISTVOYB	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/25/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The ratio between polymer and plasticizer is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claims merely setting forth physical characteristics desired in article, and not setting forth specific compositions which would meet such characteristics, are invalid as vague, indefinite, and functional since they cover any conceivable combination of ingredients either presently existing or which might be discovered in future and which would impart desired characteristics; thus, expression "a liquefiable substance having a liquefaction temperature from about 40°C. to about 300°C. and being compatible with the ingredients in the powdered detergent composition" is too broad and indefinite since it purports to cover everything which will perform the desired functions regardless of its composition, and, in effect, recites compounds by what it is desired that they do rather than what they are; expression also is too broad since it appears to read upon materials that could not possibly be used to accomplish purposes intended.—Ex parte Slob (PO BdApp) 157 USPQ 172.

In particular, the Application examined and Jun (JP 2003-012834) herein Jun disclose a composition, having Polylactic Acid of the same structure (Cargil Dow Nature Works 4060) and the same plasticizer (glycerin alkylate, see Jun line 0029 and specification, Page 20, line 15). However, physical properties of the Reference (see Comparative Example 2) are different from ones claimed in the Claim 1. Therefore, significant amount of undue experimentation requires enabling claimed invention in order to achieve the properties claimed.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ 2d 1400 (CA FC 1988).

Wands states at page 1404, the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working example and (8) the quantity of experimentation necessary.

The nature of the invention and breadth of claims

The claimed invention is a plastisized polymer composition, where the properties of the material depend on both ratio between lactic acid monomers and the amount of plastisizer in a composition. The amount of plastisizer is not defined in Claim 1, making impossible to practice the invention without undue experimentation.

The state of the prior art

In the prior art to Jun (JP 2003-012834) herein Jun or Rosenbaum et al (WO02/087877, cited with corresponding US 7144634) herein Rosenbaum. as discussed below, disclose a biodegradable flexible films, comprising as a main component a lactic acid resin composition and a plasticizer. The ratio between the L- and D-Lactide as well as amount of plastisizer varies, significantly influencing mechanical properties of the composition.

The amount of direction or guidance presented:

The Applicant does not provide any teaching regarding amount of the plastisizer in order to achieve the properties claimed in Claim 1. In Examiner's position, this teaching would be necessary, considering that type of plasticizer and it's amount is critical to achieve required properties.

The presence or absence of working example:

The Applicant presents working Examples based on only one type of plastisizer, i.e. adipic acid ester. There is no working Examples, related to any other plasticizers.

The quantity of experimentation necessary.

2. It is concluded that it would have require undue experimentation for one having ordinary skill in the art to practice the claimed invention to find appropriate step to expand the applicant's teaching to any other type of plastisizers, other than adipic acid ester to achieve required physical properties. In re Wands, 858, F.2d at 737, 8 USPQ 2d 1400, 1404 (Fed Cir. 1988)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Jun (JP 2003-012834) herein Jun or Rosenbaum et al (WO02/087877, cited with corresponding US 7144634) herein Rosenbaum.

Jun discloses a biodegradable flexible film, comprising as a main component a lactic acid resin composition comprising:

a poly(DL-lactic acid) of Molecular weight range of 50000-400000 (see line 0018) in which the proportion of L-isomer and D-isomer is 90:10 (see line 0022) and a 5-50% of plasticizer (see Abstract, line 0029), the lactic acid resin composition, wherein a value of the storage modulus (E') at 20°C is in the range of 20-700 MPa as measured at a frequency of 10 Hz by the dynamic viscoelasticity testing method from Method A of JIS K-7198 (see line 0049),

and a peak value of the loss tangent (tan delta) is in the range of 0.2 to 0.8 (see claim 2).

In reference to Claim 5, Jun teaches Hm-Hc difference of 10J/g or more (see Table 2).

Note that Jun teaches proportion of L-isomer and D-isomer is 85:15 (see Comparative Example 2, where he uses the same lactic acid as one of the Application, i.e. Cargil Dow Nature Works 4060D, see line 0059). However, the Storage Module value in this case is 65 MPA (see Table 2), which is outside of the claimed range.

Storage Module value characterizes elastic properties of the polymer and depends on its structure, molecular weight (increased Mw leads to decreasing E') and type and amount of plasticizer (the latter increases loss modulus and decreases storage modulus).

Changing L/D ratio in a polymer is one of the methods to achieve required properties such as: flexibility, orientation degree, tensile strength (especially in MD direction), etc.

Thus, mechanical characteristic of the film can be varied by both L/D isomer ratio and the amount of plasticizer present. The disadvantage of having excessive amount of plasticizer is its bleeding.

Therefore, it would have been obvious to a person of ordinary skills in the art to vary content of L-lactic isomer in a polylactic acid from 100 to 80% in order to achieve a required balance between such film parameters as flexibility, orientation degree, tensile strength (especially in MD direction), etc.

Rosenbaum teaches plasticized (glycerol fatty acid ester, the same as one of the Application, see Abstract) polylactic acid film, where content of L-Lactic acid units is within the range of 80-100% (see Column 2, line 40).

Rosenbaum teaches that D-lactic acid monomers used to decrease crystallinity degree.

Regarding Claims 1-3, 5-9, Jun or Rosenbaum do not teach the properties of the film (especially Storage modulus at 40 and 100C) within the claimed range. However, it would be obvious to a person of ordinary skills in the art that film flexibility at given polymer and plasticizer structure primarily depends on the amount of plasticizer used (a result-effective variable) (see Jun, line 0035).

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (see also MPEP 2144.05). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY LISTVOYB whose telephone number is (571)272-6105. The examiner can normally be reached on 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rabon Sergent/
Primary Examiner, Art Unit 1796

GL
